

Inventor: John C. Reed  
Serial No.: 09/350,518  
Filed: July 9, 1999  
Page 2

level of BAG-1 protein expression in a sample of said tumor or a body fluid during stage I or stage II of said cancer, wherein a high level of BAG-1 expression correlates positively with disease-free or overall survival.

---

E3 25. (Amended) A method for predicting the risk of tumor recurrence or spread in an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of BAG-1 protein expression in a sample of said tumor or body fluid from said individual during stage I or stage II of said cancer, wherein a high level of BAG-1 expression correlates negatively with tumor recurrence or spread.

---

27. (Amended) A method for screening a breast cancer patient to determine the risk of tumor metastasis or chance of survival, said method comprising:

E4 (a) determining, using a BAG-1 specific antibody, the level of expression of BAG-1 protein in a cancerous tissue sample or a body fluid sample from said patient during stage I or stage II of said cancer; and

(b) classifying a patient having high levels of expression of BAG-1 protein, relative to a reference level, as being less likely to suffer tumor metastasis or having an increased chance of survival.

---

E5 32. (Amended) The method of claim 27, wherein the amount of BAG-1 protein is measured using an immunoassay.

---

Inventor: John C. Reed  
Serial No.: 09/350,518  
Filed: July 9, 1999  
Page 3

---

34. (Amended) A method for determining the proper course of treatment for a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of BAG-1 protein expression in a cancerous tissue sample or body fluid from said patient during stage I or stage II of said cancer;

E<sup>6</sup>  
(b) identifying a first group of patients having low levels of BAG-1 expression, which first group of patients may require treatment proper for patients having a lesser chance of survival or being more likely to suffer tumor recurrence or spread; and

(c) identifying a second group of patients having high levels of BAG-1 expression, which second group of patients may require treatment proper for patients having a greater chance of survival and being less likely to suffer tumor recurrence or spread.

---

44. A method for determining risk of tumor recurrence or spread in a patient suffering from breast cancer, said method comprising:

E<sup>7</sup>  
mb  
P1  
(a) determining, using a BAG-1 specific antibody, the level of expression of BAG-1 protein in a cancerous tissue of a patient during stage I or stage II of said cancer; and

(b) classifying said patient as belonging either to a first group of patients having high levels of expression of BAG-1, or a second group of patients having low levels of expression of BAG-1,

Inventor: John C. Reed  
Serial No.: 09/350,518  
Filed: July 9, 1999  
Page 4

*Mc 177*  
wherein said first group has a lower likelihood of tumor recurrence or spread than said second group.

Please add new claims 45-56 as follows:

*Pub 1126*  
<sup>50</sup>  
~~48~~. (New) The method of claim 16, wherein said level of BAG-1 expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

<sup>51</sup>  
~~48~~. (New) The method of claim 25, wherein said level of BAG-1 expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

*Pub 1126*  
<sup>52</sup>  
~~47~~. (New) The method of claim 27, wherein said level of BAG-1 expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

*1126*  
<sup>53</sup>  
~~48~~. (New) The method of claim 34, wherein said level of BAG-1 expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

<sup>54</sup>  
~~49~~. (New) The method of claim 16, wherein said disease-free survival is distant metastasis-free survival.

*Pub 1126*  
<sup>55</sup>  
~~50~~. (New) The method of claim <sup>54</sup>~~49~~, wherein said level of BAG-1 expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

Inventor: John C. Reed  
Serial No.: 09/350,518  
Filed: July 9, 1999  
Page 5

*Rule 112b*  
<sup>51</sup> 51. (New) The method of claim 16, wherein said level of BAG-1 expression is determined by immunohistochemistry.

<sup>52</sup> 52. (New) The method of claim <sup>55</sup>50, wherein said level of BAG-1 expression is determined by immunohistochemistry.

<sup>53</sup> 53. (New) The method of claim 25, wherein said level of BAG-1 expression is determined by immunohistochemistry.

*Rule 112b*  
<sup>54</sup> 54. (New) The method of claim 27, wherein said level of BAG-1 expression is determined by immunohistochemistry.

<sup>55</sup> 55. (New) The method of claim 34, wherein said level of BAG-1 expression is determined by immunohistochemistry.

<sup>56</sup> 56. (New) The method of claim 44, wherein said level of BAG-1 expression is determined by immunohistochemistry.

REMARKS

Claims 6-8, 11-14, 16, 18-27, 29-37 and 44 are pending and under consideration. Claims 6-8, 18, 19, 29-31 and 35 have been canceled, and claims 11, 16, 25, 27, 32, 34 and 44 have been amended, without prejudice to pursuing any canceled subject matter in one or more related applications claiming benefit of priority of the subject application. New claims 45-56 have been added. Following entry of the amendments, claims 11-14, 16, 20-27, 32-34, 36, 37 and 44-56 will be pending and under consideration.